

Upcoming Ethics Grand Rounds

Wed, Dec 5th: When respecting confidentiality is risky

Wed, Feb 6th: Ancillary care: how much is enough?

Wed, April 2nd: When are conflicts of interest problematic?

Phase 1 Research

Who Should be Excluded?

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JJ

- JJ is a 9 year old from Argentina, diagnosed with metastatic Ewing's sarcoma in 2003.
- Standard treatment offers less than a 20% chance of cure, 2-3 years estimated survival, and substantial toxicity.

JJ's Parents

- Because of the low chance of cure and the high risk of toxicity, JJ's parents decide not to initiate standard therapy.
- They instead pursue aggressive surgery. JJ undergoes multiple surgeries for tumor resection.

JJ's Clinical Course

- For 4 years, JJ does very well, playing sports and going to school, exceeding his life expectancy by 1-2 years.
- Recently, JJ's has started to experience significant symptoms, including pain, and his parents express interest in research options.

Phone Contact

- JJ's physician in Argentina identifies an immunotherapy trial at the NIH which is unlikely to cause severe toxicity.
- The physician calls the NCI and recommends that the investigators screen JJ for possible enrollment.

Research Options

- The NCI team recognizes that JJ has done better than expected in response to his parents' unorthodox treatment approach.
- However, the study at the NIH is a phase 1 study and currently excludes patients who have not received standard treatment.

Past Experience

- The Phase 1 study involves a drug with promising preclinical activity in Ewing's sarcoma.
- At the time JJ is being considered, there are no data in humans that the drug has activity against Ewing's sarcoma.

Exclusion

- The NCI team believes that standard therapy has no chance of curing JJ, but offers a good chance (>50%?) for symptom improvement and life prolongation.
- Some members conclude it would be unethical to enroll JJ since he has not received "standard therapy."

Inclusion

- Other members of the team conclude that it is unethical to exclude JJ from the Phase 1 study.
- They argue that there is no treatment that offers a chance for cure and he/his parents prefer the phase 1 study because of the low likelihood of toxicity.

Bioethics Consultation

- The team calls a bioethics consultation to discuss the case.

Questions

- How should the team respond to the request to screen JJ for enrollment?
- Should they recommend against it, but allow the parents/JJ to make the final decision?
- Should the team exclude JJ given that he has not received standard treatment?